United States Patent [19]

Compere

[11] **3,921,805**

[45] **Nov. 25, 1975**

[54] **RUPTURABLE BLISTER PILL PACKAGE WITH SAFETY BACKING**

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[22] Filed: **July 9, 1973**

[21] Appl. No.: **377,326**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 296,192, Oct. 10, 1972, Pat. No. 3,809,221.

[52] **U.S. Cl.** **206/532;** 206/469; 206/484; 206/820

[51] **Int. Cl.²** **B65D 73/00;** B65D 83/04

[58] **Field of Search** 206/461, 498, 484, 820, 206/42, 532, 469

[56] **References Cited**

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[57] **ABSTRACT**

A rupturable press-through blister type medicament or pill package is "childproofed" by securing to the blister sheet a laminated backing sheet having at least one strong flexible polyester layer so that the pill cannot be forced through the package unless the backing sheet is first peeled away. The blister sheet and backing sheet are left unsealed in a predetermined area to provide easier access to the package contents.

3 Claims, 6 Drawing Figures

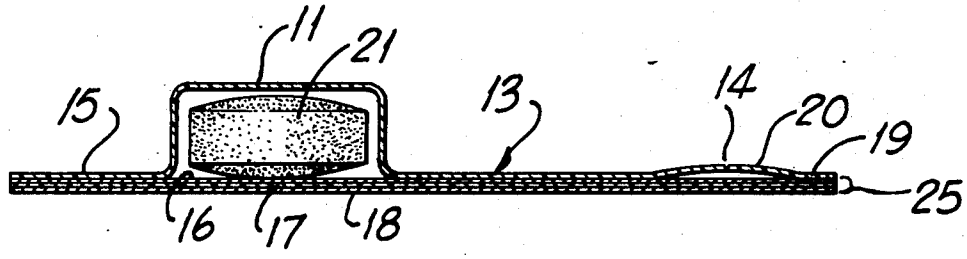


Fig. 1

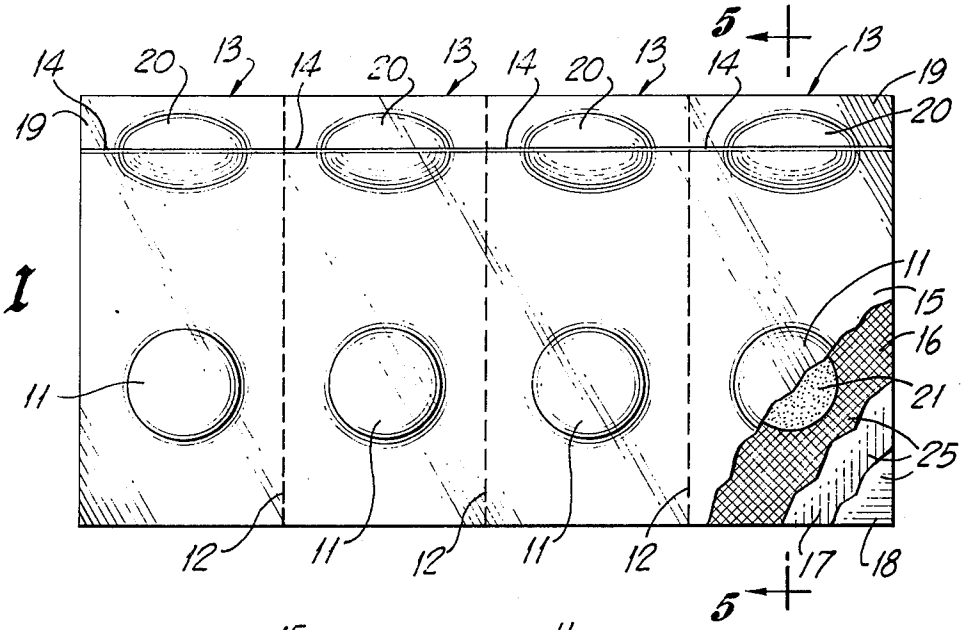


Fig. 2

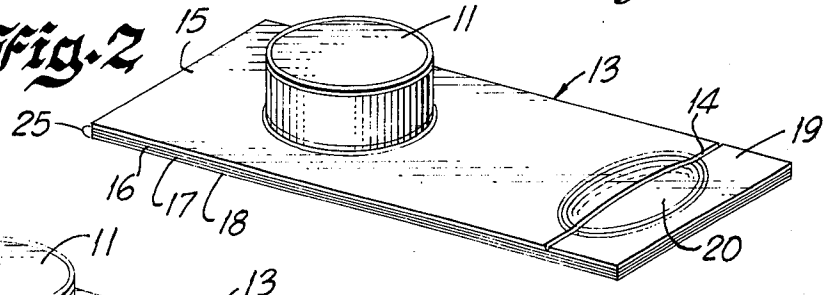


Fig. 3

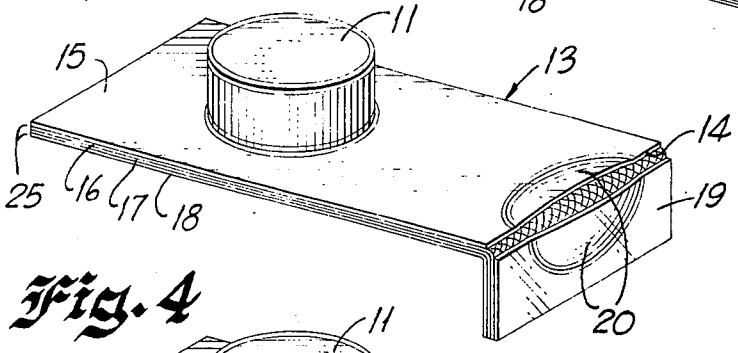


Fig. 4

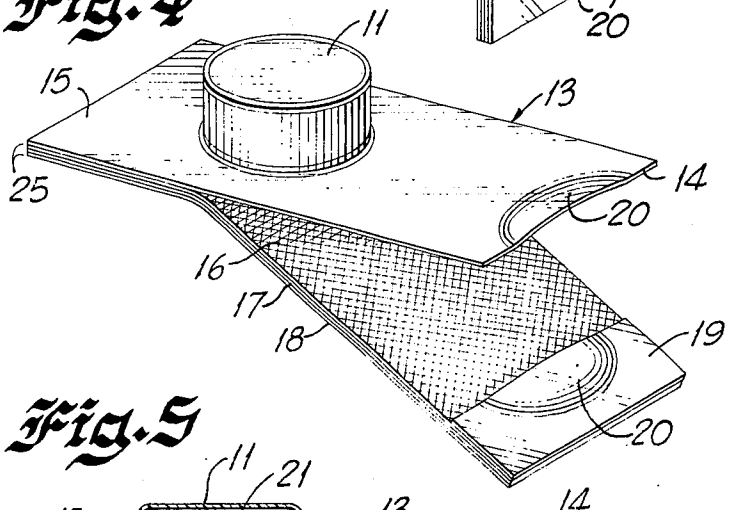


Fig. 5

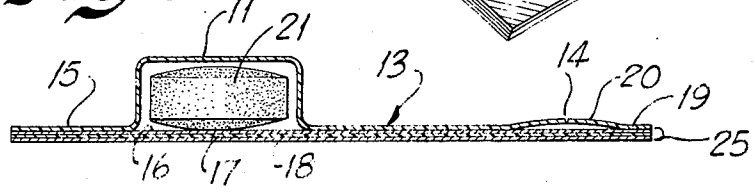
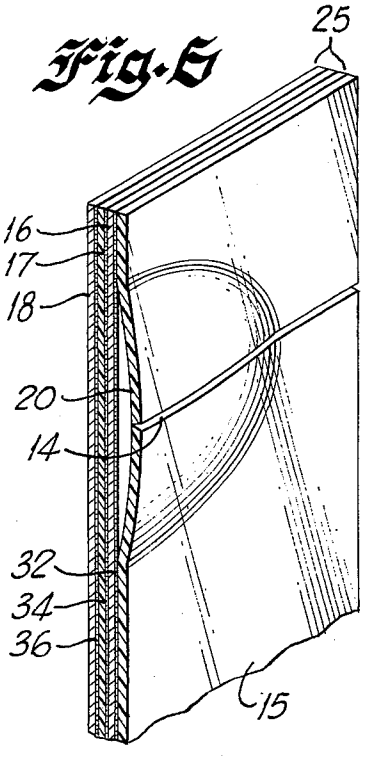


Fig. 6



RUPTURABLE BLISTER PILL PACKAGE WITH SAFETY BACKING

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of my co-pending application Ser. No. 296,192 entitled Rupturable Blister Pill Package with Safety Backing, filed Oct. 10, 1972.

BACKGROUND OF THE INVENTION

The present invention relates to a safety blister-type package for enclosing medication or pills. As disclosed in my co-pending application Ser. No. 296,192, now U.S. Pat. No. 3,809,221, one of the problems facing today's parents is in keeping medication or pills beyond the reach of their children. Children do not have the ability to recognize the risk involved in consuming unprescribed medication. Because of this fact, there is an urgent need for a package from which pills are readily accessible to the adult, but not accessible to the child.

Press-through packs or blister packs are commonly used today to package units of medication or pills for oral ingestion. The press-through package is made up of a first sheet, typically a clear, preformed polyvinyl chloride or polystyrene with flexible bubbles which form separate compartments for one or more pills; and a second rupturable sheet material, like an aluminum foil or paper sheet, which has been attached to the first sheet. The metal foil is attached by heat-sealing, solvent welding, gluing, or otherwise adhering the foil sheet to the blister sheet. The tablet is removed from the blister compartments by pressing on the flexible blister which in turn forces the tablet against the foil, rupturing the foil, and ejecting the tablet.

It is sometimes desirable in making such a press-through package to include between the first and second sheets a rigid tray in which there are holes which coincide with the blisters in said first sheet. The rigid tray is used to protect the pills from contamination and mechanical damage and may contain printed instructions as to the type of pill or the time a particular dosage is to be taken and with an indication of the dosage that has already been taken.

The recent trend in the packaging of medication has been to provide packages which will be safe, even if found by children. Most developments in the "childproofing" line have been directed to the improvement in pill bottles. In this regard, safety caps have been devised which require a certain series of pushes and turns in order to open the bottle. However, there has been little development in the area of "childproofed" press-type blister packages with which this invention is concerned.

PRIOR ART

Prior art packages which have used more than one backing layer on a press-through blister-type package have not used a layer of backing material which cannot be ruptured. The prior art backing layers which have been used to cover the rupturable layer, have been made from paper or foil and may have been scored or weakened so that all backing layers can be ruptured to press a pill through the package. These additional prior art backing layers have been used for the purposes of providing printed information on the back of the pill package and for additional sealing engagement to protect the pills from the environment. For example, see

the following U.S. Pat. Nos.: Nagy, 3,503,493; Osborn, 3,621,992; Sorensen, 2,317,860; and Heller, 3,387,699. In each of these patents the multiple backing layers used on the blister or press-through type pill package can be easily ruptured or peeled away and are not strong enough to provide "childproofing".

One attempt at "childproofing", a blister-type pill package, can be seen in the Helstrom U.S. Pat. No. 3,472,368. In this patent, there is no second backing member which is peeled away to expose the rupturable layer as will be disclosed in describing the present invention. This package is supposedly "childproofed"-"simply by providing a rupturable sheet which is very difficultly ruptured. The Helstrom patent, therefore, relies on the child's weakness as the necessary element to prevent him from opening the package.

FIELD OF THE INVENTION

The present invention was developed with the idea of providing a pill package which requires knowledge of the package opening procedure rather than a minimum amount of strength for opening said package. The person who is likely to be taking pills is not generally in a very strong physical condition. Quite often, the strength of a child is greater than the strength of the person who is ill and most likely to be taking pills. Because of this fact, this invention was developed to provide a pill package which can be opened by the instructed adult who may have no more strength than the average child. The child who is uninstructed on the opening of the herein disclosed package will not be able to reach the package contents. The present invention, therefore, relies on the superior knowledge of the adult rather than his superior strength in order to make a package which is easily opened by the adult but cannot be opened by the child.

A primary object of the present invention is to provide a "childproof"pill package which can be easily opened by one who has been given instructions on how to do so, but cannot be opened by the uninstructed child.

Another object of the present invention is to provide a pill package which, when opened, makes only one dosage of pills accessible to the user, which dosage, of course, is less than a lethal dosage.

Another object of the present invention is to provide a pill package in which any desired number of pills can be made accessible upon opening.

Another object of the present invention is to provide a pill or medication dispensing package in which each pill or dosage of medication is almost entirely visible to the user.

Another object of the present invention is to provide a pill package in which one pill or one dosage of pills can be removed from the package while the remaining pills can be maintained in an air-tight enclosure.

Another object of the present invention is to provide a pill package in which the use of cumbersome bottles is not required.

Another object of the present invention is to provide a pill package in which each individual pill can be separately packaged so that the desired dosage can be carried by the user without the necessity of carrying excess pills.

Another object of the present invention is to provide a pill package which requires additional package opening to remove each additional pill.

Another object of the present invention is to provide a safety pill package which the child cannot open without the aid of tools.

Yet another object of the present invention is to provide a pill package in which opening of the package makes accessible a less than dangerous number of units of medication. The number of units exposed upon each opening of the package can be varied depending upon the toxicity of the packaged medication.

The present invention is concerned with a safety press-type blister package which is similar to the common blister package, but which has a strong backing sheet which encloses each blister. The strong flexible backing sheet is secured to the back of the blister sheet in such a manner that when secured, the backing sheet is not pushed away from the blister sheet when pressure is put on the blister-side of the pill package in an attempt to push the pill through the package. For the user to be able to remove a pill from the package, the strong backing sheet must first be peeled away. So long as the required adherence is obtained, the strong backing sheet can be secured to the blister sheet by heat sealing, solvent welding, gluing or otherwise adhering the two sheets together. A preferred method is by heat-sealing.

There are hundreds of heat-seal coating formulations which can be used to provide heat-sealability between the layers of the package laminate of the present invention. These heat-seal formulations are commonly used in making foil/paper and resin sheet/resin sheet laminates for soap wraps, carton overwraps, cereal liners, cookie wraps, and other uses. The heat-seal formulations are typically a water dispersion of a vinyl resin or a vinyl resin containing wax for providing lower heat-sealing temperatures. The vinyl resin can be ion-linked and acid-modified ethylene interpolymers known as ionomer resins. Wax and other modifiers further extend the range of performance properties.

The preferred heat-seal formulations are water dispersions of ethylene interpolymers — for example ethylene/vinyl acetate interpolymers. The vinyl resin formulations combine broad adhesion properties with moderate hot tack. Modifiers such as pigments, waxes or other resins can be used.

It is preferred to apply the heat-seal coatings in an amount of about 2½ to 4 lbs. per ream. The coatings can be applied by common methods, for example, curtain coating or roller coatings as known in the art.

The blister sheet is made in a known manner and is made from common blister sheet material such as polyvinyl chloride, and copolymers and terpolymers of vinyl chloride, for example the terpolymer of polyvinyl chloride/polyethlene/polypropylene.

The backing sheet must have a layer or sheet of a strong flexible polymeric material of sufficient strength that a pill cannot be hand-forced through the polymeric material. A sheet of polyester material has been found to have sufficient strength to prevent a pill from being forced therethrough. A preferred polyester material is polyethylene terephthalate.

A foil sheet can also be used as part of the backing sheet if a barrier resistance coating is needed to prevent moisture from penetrating into the blister. A metal foil, such as aluminum, having a thickness as small as 0.001 inch is sufficient.

A sheet of paper for the purpose of printing may also form part of the backing sheet. Bleached kraft having a basis weight of 20–25 pounds is preferred. Dates, numbers, or a description of the package contents can be printed on the paper for consumer information.

The various layers comprising the backing sheet can be laminated to form a single laminated sheet prior to applying the backing sheet to the blister sheet, or the backing layers can be secured together at the same time they are adhered to the blister sheet. The preferred method of laminating is by using heat-seal coatings, as previously described. It is usually desirable to provide a paper sheet as the sheet farthest from the blister sheet so that printing is easily read from the bottom or non-blister side of the package. However, if it is not necessary to prevent moisture penetration into the blister, the printed paper can be positioned next to the transparent blister sheet and read through the blister sheet from the top of the package.

The strong polymeric sheet, foil sheet, and paper can be applied to the blister sheet in any order except that the paper sheet cannot be positioned next to the blister sheet if it is necessary to prevent moisture from entering the blister. Thus, the strong polymeric sheet can be positioned next to the blister sheet or intermediate between the foil and paper sheet, or as the sheet farthest from the blister. If the paper sheet is between the foil and strong polymeric sheet, the polymeric sheet would have to be transparent so that printing on the paper can be read by the consumer.

When applied as a single lamination structure, the layers of the backing sheet can be secured together by heat-sealing, solvent welding, gluing, applying sheets of adhesive materials between the layers, or otherwise adhering the layers together. For example, a sheet of extruded polyethylene can be included between the sheet of strong flexible material and the foil sheet and likewise between the foil and paper sheet. The extruded polyethylene will adhere the three sheets together upon the application of pressure without the necessity of heat-sealing. It is preferred to use an extruded polyethylene sheet or film with a weight of about 10 lbs. per ream. Heat-seal coatings can be used in addition to intermediate adhesive layers.

After securing the blister sheet to the backing sheet, the backing sheet cannot be forced to disengage the blister sheet by applying pressure on the pill from the bister-side of the packet. However, the backing sheet can readily be peeled from the back of the package so that the blister contents can be removed. The seal between the blister sheet and backing sheet must be strong enough so that when pressure is applied to the blister, the flexible backing sheet remains in contact with the blister sheet. The backing must be strong enough so that with the backing sheet engaged, a pill cannot be forced through the backing sheet by applying pressure to the pill from the blister-side of said package.

A strong polyester which has been found particularly effective as at least one component of the backing sheet is polyethylene terephthalate. The thickness of the polyester is preferably about 50 gauge. However, any plastic with strength sufficient to prevent a pill from being hand-forced therethrough can be used for this purpose.

A weakened severance line is provided across any edge of the package (top, bottom or either side). The weakened severance line is made in the blister sheet but usually not in any layers of the backing sheet.

The weakened severance line is provided by making a perforated score line, thinner portion or the like

which extends across any edge of the package. This weakened severance line extends through the blister sheet only so that when the package is angulated or flexed at the line of weakening, the forces cause the blister sheet to be severed at the line of weakening. The smaller severed portion of the blister sheet is still bonded to the backing sheet and together with said backing sheet, acts as a tab for peeling the backing sheet from the package.

The weakened severance line is perferably positioned along a shorter edge of the package so that when the backing sheet is peeled, the contents of only one blister is exposed at a time. Taking into account the persistence and endurance of a child who has made up his mind to open the package, the weakened severance lines can be made severable only by a series of angular back-and-forth flexing at said severance lines. In this regard, only a few short perforations need be made to create severability for the instructed adult. Further, rather than a line of intermittant perforations, only a crushing force need be applied to create a line of weakening so that the blister sheet will be made thinner along the line of crushing. The crushing force will cause a decrease in strength of the blister sheet so that severance will occur with back-and-forth angular flexing at the severance line. Of course, the smaller the weakening effect along the severance line, the safer the package and the more difficult the package will be for the adult to open. It is within the skill of the art to create a severance line in accordance with the above disclosure which makes the package prohibitively difficult for the uninstructed child to open, but is not unduly burdensome for the adult to open.

Given instructions on how to peel off the backing sheet, the user can then flex or bend the edge of the package along the line of weakening so that the blister sheet becomes severed along the weakened severance line. By grasping this separated tab or edge of the package and tearing downward parallel to the back-side of the package, the user can peel off the strong flexible backing sheet and thereby expose the blister contents.

It is desirable to provide an unsealed area between the blister sheet and backing sheet directly below the line of weakening in the blister sheet. In this manner, the severance of the blister sheet along the line of weakening will expose an unsealed area helpful to initiate the separation of backing sheet from blister sheet. The unsealed area should not extend to the blister or to any edge of the package. If the unsealed area extends to the blister, the package contents will be contaminated and too easily accessible. If the unsealed area extends to the package edge, the package contents again will be too readily accessible since the package can be opened without first peeling away the blister sheet.

The unsealed area can be provided in a number of ways. When the backing sheet is laminated to the blister sheet, pressure can be omitted from a predetermined area corresponding to the unsealed area. Without pressure to laminate the backing sheet to the blister sheet in the predetermined area, that area will not be sealed. Other methods of providing the unsealed area include omitting a heat-seal coating between the backing sheet and blister sheet in a predetermined area so that with the application of heat and/or pressure, the sheets are not sealed in that area. In the same manner, adhesive coatings and extruded polyethylene adhesive layers can be applied between blister sheet and backing sheet so that a predetermined area is not covered and the sheets will therefore not be adhered in the non-covered area.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The invention together with the above and other objects may be best understood from a consideration of the following detailed description of an illustrative embodiment in the course of which reference is had to the accompanying drawings in which:

FIG. **1** is an enlarged plan view of the safety blister package of the present invention showing multiple pill packets in one package;

FIG. **2** is a perspective view of one of the pill packets shown in FIG. **1**;

FIG. **3** is a perspective view of one of the pill packets of FIG. **1** in which the pill packet is partially opened;

FIG. **4** is a cross sectional view taken along line **4—4** of FIG. **1**;

FIG. **5** is an enlarged fragmentary cross sectional view better illustrating the various layers, adhesive, and unsealed area of the pill packets shown in the previous figures.

Referring to the drawings and first to FIG. **1**, a safety blister package is indicated as a whole by the reference character **10.** The package **10** may contain multiple sub-packages or packets **13** having one or more blisters **11** of any desired shape which conform to the shape of the particular medicament or pill **21** contained within said blister. The sub-packages or packets **13** can be separated from each other by severing the package at lines of weakening or perforated score lines **12.** Along one edge of each packet **13,** a line of weakening **14** in the blister sheet **15** is provided for opening each packet. Directly under the line of weakening **14** there is an unsealed area **20** in which the blister sheet **15** has not been sealed as by heat and/or pressure to the sheet directly therebelow. Thus, when the edge of the packet **13** is angulated or flexed along line of weakening **14,** the blister sheet **15** is severed along line **14** to expose the unsealed area **20.** The packet **13** can thereby be more easily opened by inserting the finger into the unsealed area **20** to aid in peeling back the backing sheet **25.**

Backing sheet **25** as shown in FIGS. **2, 3** and **4** contain a foil barrier sheet **16,** a sheet of a strong flexible polymeric material for example a polyester such as polyethylene terephthalate **17,** and a paper sheet **18** which can have printing thereon to convey information to the consumer such as the package contents. FIG. **2** shows tab **19** which is formed by angulating or flexing the edge of the package along line of weakening **14** as explained above.

As previously set forth, the backing sheet **25** need not contain all three layers of foil, strong flexible polymeric material and paper. However, the strong polymeric material is necessary for the purpose of providing a safety backing to the blister sheet **15** so that the pills **21** can not be forced out of the package without first peeling the backing sheet **25** from the blister sheet **15.**

The layers **16, 17** and **18** of the backing sheet **25** can be secured together by heat sealing, solvent welding, gluing, applying sheets of adhesive materials between the layers, or otherwise adhering the layers together. FIG. **5** shows one embodiment of adhering the blister, foil, strong flexible polymeric material, and paper layers together by means of adhesive layers **32, 34,** and **36.** These adhesive layers **32, 34** and **36** can be applied in

liquid form or may be applied as a sheet of material, for example, polyethylene which is made adhesive by the application of heat and/or pressure. Adhesive layer **32** between the blister sheet **15** and first layer of backing sheet **16** should be a heat-seal coating so that blister sheet **15** may be heat sealed to backing sheet **25.**

The package as described herein complies with standards of the Poison Prevention Packaging Act, 21 CFR 295.1, which describes the test procedures in which the packages are given to children for a given period of time to determine accessibility of the package contents.

It should be understood that the printing on the paper sheet can contain any desired information such as a description of the item contained within the blister, and numbers or dates for sequential dosages. In this regard, the package can be calendarized as commonly seen in oral contraceptive packages and in fact can be used to package oral contraceptives. Of course, the package need not be in a rectangular form as shown in the drawings. The package can be circular having severance lines between individual pill packets which extend from the center of the circular package forming pie-shaped individual packets containing as many items as desired. In this manner, any desired shape can be used with severance lines between individual packets placed to give individual packets containing as many items as desired.

While the present invention has been described with reference to a medicament or pill, it can also be used to make a child-resistant package for capsules, tablets, troches, suppositories, etc.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. A protective childproof package comprising:

a first sheet having one or more flexible blisters which form compartments, each blister being adapted to receive a medicament; and having a line of weakening along one edge; and

a backing sheet closing and sealing the compartments formed by the blisters in the first sheet and being secured to the first sheet along each edge of said first sheet and over substantially the entire backing sheet surface area except at each blister and at an unsecured area directly under the line of weakening;

said backing sheet comprising a laminated sheet of a foil sheet, a sheet of polyethylene terephthalate, and a sheet of paper wherein the backing sheet is secured together with intermediate sheets of polyethylene as an adhesive;

said backing sheet secured to said first sheet such that said backing sheet cannot be forced out of engagement with said first sheet when force is applied to said flexible blisters;

said backing sheet having at least one sheet of material therein which has sufficient strength so that the backing sheet can neither be ruptured nor forced out of engagement with the first sheet when force is applied to the medicament from the blister side of the package.

2. A protective childproof package as defined by claim **1** wherein the first sheet is secured to the backing sheet with a heat seal coating.

3. A protective childproof package comprising:

a first sheet having one or more flexible blisters which form compartments, each blister being adapted to receive medicament; and having a line of weakening along one edge; and

a backing sheet closing and sealing the compartments formed by the blisters in the first sheet and being secured to the first sheet along each edge of said first sheet and over substantially the entire backing sheet surface area except at each blister and at an unsecured area directly under the line of weakening;

said backing sheet comprising a foil sheet, a sheet of polyethylene terephthalate, and a sheet of paper wherein the backing sheet is secured together with intermediate layers of an adhesive;

said backing sheet secured to said first sheet such that said backing sheet cannot be forced out of engagement with said first sheet when force is applied to said flexible blisters;

said backing sheet having at least one sheet of material therein which has sufficient strength so that the backing sheet can neither be ruptured nor forced out of engagement with the first sheet when force is applied to the medicament from the blister side of the package.

* * * * *